UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: JOHNSON & JOHNSON TALCUM POWDER PRODUCTS MARKETING, SALES PRACTICES, AND PRODUCTS LIABILITY LITIGATION	**MDL No. 16-2738 (MAS)(RLS)**
THIS DOCUMENT RELATES TO ALL CASES	

THE PLAINTIFFS' STEERING COMMITTEE'S MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION TO EXCLUDE THE ASBESTOS TESTING OPINIONS OF MATTHEW S. SANCHEZ, PH.D., ANN G. WYLIE, PH.D. AND SHU-CHUN SU, PH.D.

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I. Introduction

The Plaintiffs' Steering Committee ("PSC") respectfully submits this motion, under Fed. R. Evid. 104(a), 702, 703 and 403, to exclude the opinions and testimony of Defendants' experts, Matthew S. Sanchez, Ph.D., Ann G. Wylie, Ph.D. and Shu-Chun Su, Ph.D. Defendants tasked each of them with critiquing the testing methodology and conclusions of Plaintiffs' expert, William E. Longo, Ph.D.

Using polarized light microscopy ("PLM"), Dr. Longo detected chrysotile asbestos in samples of Johnson's Baby Powder. While others too, including those testing samples of talc at the behest of Johnson & Johnson, have also reported finding asbestos, Drs. Sanchez, Wylie, and Su ignored the decades of positive test results. Rather than perform a comprehensive assessment of the evidence of asbestos in Johnson's Baby Powder, Drs. Sanchez, Wylie, and Su have offered competing, and at times, contradictory, critiques of Dr. Longo's testing and opinions, which are subjective, speculative, and rely on geologic/mineralogic definitions of "asbestos" that are overly restrictive. As expert testimony should only reach jurors if it is reliable and fits the issues in the case, the opinions of Drs. Sanchez, Wylie, and Su on the methodology and conclusions of Dr. Longo should be excluded. Dr. Su's opinion should also be excluded as Rule 26(a)(2) does not allow parties to cure deficient expert reports by supplementing them with later deposition testimony as Dr. Su has attempted to do here.

Defendants also commissioned Dr. Sanchez to critique the opinions of Plaintiffs' experts, David A. Kessler, M.D., J.D., a former commissioner of the Food and Drug Administration ("FDA"), and William Sage, M.D., J.D. According to Dr. Kessler, a determination by a laboratory that certain amphibole particles were non-asbestiform does not mean that the safety of those particles has been substantiated. As Dr. Sanchez is neither a medical doctor nor epidemiologist and has not comprehensively reviewed the literature on the health effects of what he defines as "non-asbestiform" particles, Dr. Sanchez is not qualified to opine on Dr. Kessler's opinions. Dr. Sanchez also fails to appreciate that it does not matter whether some tests of Johnson's Baby Powder failed to detect asbestos. Dr. Kessler opined that because some tests had, Johnson & Johnson failed to substantiate the safety of its product under the FDA's regulations. Dr. Sage similarly opined that the threshold is low for when cosmetics manufactures are required to warn consumers of possible hazards and due to the potential health hazard from talc, Johnson & Johnson marketed and sold a misbranded and adulterated product. Dr. Sanchez's opinions should be excluded for these reasons too.

II. Factual Background

A. Plaintiffs' Experts

1. William E. Longo, Ph.D.

Dr. William E. Longo has a Bachelor of Science degree in Microbiology, a Master of Science degree in Engineering, and a Doctorate in Philosophy in Materials

Science, from the University of Florida. According to Judge Wolfson in the April 27, 2020 *Daubert* Opinion, "[t]here is no dispute that Dr. Longo is qualified to testify as an expert on the issue of whether the subject talc products contain asbestos."[1]

Since Dr. Longo issued his February 1, 2019 Second Supplemental Report (**Exhibit 1**), which Judge Wolfson considered in the April 27, 2020 *Daubert* Opinion,[2] Dr. Longo tested 43 additional samples, which are discussed in his Third and Fourth Supplemental Reports.[3] As Dr. Longo explains, when the last MDL report was issued, his company, Material Analytical Services, LLC ("MAS"), was not analyzing cosmetic talc samples using the heavy liquid separation ("HLS") sample preparation method.[4] That sample preparation methodology, which had first been developed by the Colorado School of Mines, is a mineral separation method that uses high density liquids and centrifugation to separate minerals thereby increasing detection limits. Of the samples discussed in the Fourth Supplemental Report, Dr. Longo found chrysotile or amphibole asbestos in 93% of them.

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[1] *In re Johnson & Johnson Talcum Powder Prod. Mktg., Sales Pracs. & Prod. Litig.*, 509 F. Supp. 3d 116, 147 (D.N.J. 2020).

[2] *Id.* at 147.

[3] The Fourth Supplemental Report 4/29/24 (**Exhibit 2**) corrects certain typographical errors in the Third Supplemental Report 11/17/23 **(Exhibit 3)**.

[4] **Exhibit 2**, 4/29/2024 Longo Report, pgs. 2-8.

2. David A. Kessler, M.D., J.D.,

Dr. David A. Kessler is a former FDA Commissioner and presently, a professor of Pediatrics and Epidemiology, and Biostatistics at University of California, San Francisco.[5] He graduated with and M.D. degree from Harvard Medical School and a J.D. degree from the University of Chicago.[6] In addition to his research and teaching on epidemiology, Dr. Kessler has also taught courses on food and drug law and published many articles in legal, medical, and scientific journals on the federal regulation of food, drugs, and medical devices.[7]

According to Dr. Kessler, the FDA's regulations—specifically, 21 CFR § 740.10—require cosmetic manufacturers to substantiate the safety of their products.[8] Based on his review of decades of testing data since the 1970s, Dr. Kessler found that the safety of Johnson's Baby Powder has "not been substantiated."[9] He accordingly opined that a reasonable and prudent manufacturer would have warned the public, reformulated or stopped selling the product, and improved the sensitivity of its testing so as not to put the public at risk.[10] Dr. Kessler thus opined that this

[5] **Exhibit 4**, 11/15/2023 Kessler Report, ¶¶ 3-4.

[6] *Id.*, ¶ 1.

[7] *Id.*, ¶ 6.

[8] *Id.*, ¶ 27 (citing 21 CFR § 740.10).

[9] *Id.*, pg. 117 ¶ 10.

[10] *Id.*, pg. 116-20.

"failure to adopt a public health approach to asbestos in talc testing, even if that led to over-inclusion and false positives, put consumers at risk.[11]

3. William Sage, M.D., J.D.

Dr. William Sage is an Assistant Vice President in the Texas A&M University Health Science Center.[12] He is also a Professor of Law at Texas A&M University School of Law in Fort Worth, Texas, a Professor of Translational Medical Science at Texas A&M University School of Medicine, and a Professor at the Bush School of Government and Public Service at Texas A&M University.[13] He received an A.B. in biochemical sciences from Harvard College, an M.D. with research honors in anesthesia and critical care medicine and a J.D. from Stanford University.[14]

According to Dr. Sage, "Cosmetics manufacturers must warn consumers of possible health hazards, with the law applying a low threshold for disclosure of risk and uncertainty because cosmetics have no offsetting health benefits and because studies are infrequent and poorly funded compared to drugs."[15] Citing 21 C.F.R. § 740.10(a), Dr. Sage added that "cosmetics manufacturers are specifically required to

[11] *Id.*, pg. 121 ¶ 34.

[12] **Exhibit 5**, 11/15/2023 Sage Report, ¶ 1.

[13] *Id.*, ¶ 1.

[14] *Id.*, ¶ 2.

[15] *Id.*, ¶ 74 (citing 21 C.F.R. §§ 740.1, *et seq.*).

disclose uncertainty regarding product safety, even if a risk has not been definitively established or quantified."[16, 17]

Based on a review of test results, evidence that talc particles can reach the ovaries, and epidemiology, Dr. Sage observed that there has long been "a potential health hazard from talc powder."[18] As for whether Johnson & Johnson complied with these standards, Dr. Sage observed that Johnson & Johnson "has not applied a 'safety not determined' label to its talcum powder products notwithstanding lack of prior substantiation for safety and new information repeatedly demonstrating a hazard to human health."[19] Dr. Sage also opined that Johnson & Johnson did not "respond to or notify FDA of information that its talcum powder products and their ingredients may be associated with a health hazard," "supply required warnings to consumers," "register its cosmetics accurately," and "inform FDA of positive testing results."[20] Dr. Sage thus concluded that Johnson & Johnson "marketed and sold a misbranded and adulterated product."[21]

[16] *Id.*, ¶ 81.

[17] Dr. Sage explained that "[r]isk is a known and quantifiable probability (statistical likelihood) of harm; uncertainty is a lack of knowledge about the existence or magnitude of risk." *Id.*, ¶ 45.

[18] *Id.*, ¶¶ 45, 50-61, 85-99, 116-125.

[19] *Id.*, ¶ 83.

[20] *Id.*, ¶¶ 176-180.

[21] *Id.*, ¶ 181.

B. Defendants' Experts

1. Shu-Chun Su, Ph.D.

Dr. Shu-Chun Su has a Ph.D. in geology, has authored 29 publications on asbestos analysis, and developed the "Su Method," which uses central stop dispersion staining by PLM to fingerprint asbestos.[22] While Dr. Su had described that method as "accurate" in both his publications and report, he repudiated that position in his deposition testimony, claiming for the first time that it is necessary to cross-reference the results from that approach with a Becke line analysis.[23] Aside from describing tests using the Becke line analysis that he performed for the first time after issuing his report, Dr. Su also reported performing several other tests after he issued his report, all of which, he could have performed before issuing his report.

Illustrating the lack of data on which he based his conclusions, Dr. Su opined that Dr. Longo's refractive index measurements fall outside the accepted range for chrysotile asbestos, (**Exhibit 8**, 7/18/2024 Su. Tr., 303:25 – 304:12). In his report, Dr. Su explained that Dr. Longo's measurements far exceeded those of the NIST SRM 1866 standard.[24] Yet in his academic writing, Dr. Su acknowledged that "there

[22] **Exhibit 6**, 5/21/2024 Su Report, pg. 2.

[23] **Exhibit 7**, 7/11/2024 Su Tr., T100:3-14.

[24] **Exhibit 6**, 5/21/2024 Su Report, pg. 2.

are chrysotile minerals whose RIs are significantly higher than those of the standard chrysotile from the NIST SRM 1866 set."[25]

2. Matthew S. Sanchez, Ph.D.

Dr. Matthew S. Sanchez earned a Ph.D. in geology from the University of Idaho[26] and is presently a principal investor with the RJ Lee Group, Inc. He offers three opinions in this case: one concerns Dr. Longo's reports and the other two, Dr. Kessler and Dr. Sage's reports. In addressing Dr. Longo's report, Dr. Sanchez relies on four epidemiological studies to define the morphological characteristics of asbestos even though he is neither an epidemiologist nor a healthcare professional.[27] He also relies on certain historical testing result as the basis for his opinion,[28] but ignores many contrary test results, including ones reporting the presence of chrysotile asbestos.[29] Besides cherry-picking data, Dr. Sanchez also disregards the

[25] **Exhibit 9**, pg. 56.

[26] **Exhibit 11**, Sanchez CV.

[27] **Exhibit 10**, 3/26/24 Sanchez Report pg. 5; **Exhibit 12**, 6/25/2024 Sanchez Tr., 53:19:-20, T251:7-9.

[28] **Exhibit 10**, pg. 11.

[29] *See* **Exhibit 13** (identifying test results of chrysotile asbestos: 3/9/1971 McCrone ;10/12/1971 McCrone; 1972 University of Minnesota; 8/24/1972 Sperry Rand (hired by the FDA); 8/3/1972 Dr. Weissler (hired by the FDA); 1/29/1974 McCrone; 3/11/1974 McCrone; 4/10/1974 McCrone; 4/24/1974 McCrone; 5/8/1974 McCrone; 7/1/1975 McCrone; 10/6/1978 McCrone; 8/22/1985 McCrone; 4/29/1986 McCrone; 3/14/1988 RJ Lee; 11/26/1990 McCrone).

limitations of OSHA ID 191,[30] EPA600/R-93/116,[31] and ISO 22262-1,[32] in defining what constitutes "asbestos." His approach to asbestos testing is therefore overly restrictive and given the fluidity with which he defines what a "population" is, also subjective and unreliable. These issues carry over to Dr. Sanchez's critique of Drs. Kessler and Sage's reports,[33] thus rendering those critiques unreliable.

3. Ann G. Wylie, Ph.D.

Dr. Ann G. Wylie was a professor of Geology at the University of Maryland until her retirement in 2014. She is not an "analyst,"[34] and does not do "routine analysis of cosmetic talc."[35] Over her career, she has only tested two samples of Johnson's Baby Powder.[36] According to Dr. Wylie, in order to assess whether an unknown substance is asbestos, eleven morphological properties must be considered.[37] She however testified to not being aware of any standards requiring consideration of each of the eleven properties specific to cosmetic talc and

[30] **Exhibit 14** OSHA ID 191.

[31] **Exhibit 15** EPA600/R-93/116.

[32] **Exhibit 16** ISO 22262-1.

[33] **Exhibit 17**, 4/1/2024 Sanchez Report; **Exhibit 18**, 4/1/2024 Sanchez Report.

[34] **Exhibit 21**, 6/24/2024 Wylie Tr., T31:20.

[35] *Id.*, T32:10-15.

[36] *Id.*, T10:8 to T11:7. Dr. Wylie has testified that other than these two samples, she has not tested any other cosmetic talc products for asbestos. *Id.*, T19:10-24.

[37] Those include the (1) optical group, (2) indices of refraction, (3) birefringence, (4) size and sign of the optical axial angle in biaxial minerals, (5) dispersion of the optic axes, (6) orientation of principle indices of refraction and cleavage, (7) color, (8) relief, (9) form, (10) sign of elongation, and the (11) extinction angle. **Exhibit 19**, Wylie 5/3/2024 Report, pg. 4.

asbestos.[38] And in testing the two samples of Johnson's Baby Power, Dr. Wylie did not address all eleven morphological characteristics, contrary to her own stated methodology.[39]

Rather than test talcum powder samples, Dr. Wylie only reviewed the "raw data" generated by Dr. Longo.[40] While she claimed that she had sufficient data to render her conclusions, she did not consider all eleven morphological properties and otherwise speculated about a number of issues, such as the light source used by Dr. Longo[41] and whether Dr. Longo sufficiently heated the samples to remove organic compounds.[42] Dr. Wylie nonetheless testified that she "saw nothing in the reports about sample preparation with which [she] found a problem."[43] She instead claims that what Dr. Longo had identified as asbestos was talc based on her own analysis of a sample of Calidria asbestos, even though she could not establish that the one she analyzed resembled those Dr. Longo analyzed.[44]

[38] **Exhibit 21**, 6/24/2024 Wylie Tr., T35:24 to T36:9.

[39] *Id.*, T14:3-11.

[40] *Id.*, T98:17-24.

[41] **Exhibit 19**, Wylie 5/3/2024 Report, pg. 2.

[42] *Id.*, pg. 37.

[43] **Exhibit 21**, 6/24/2024 Wylie Tr., T106:15-18.

[44] *Id.*, T64:11 to T65:15.

III. Legal Standards

The PSC incorporates the legal standards set forth in the Plaintiffs' Steering Committee's Memorandum of Law Regarding the Rule 702 Standard ("Rule 702 Standard Brief").

IV. Argument

The standard for qualifying experts, though "liberal," "is not a mere formality."[45] As there is "a floor with respect to an expert's qualification," not every witness proffered should qualify as an expert.[46] An expert witness, for instance, may not opine on matters that are outside the area of his expertise. Therefore, even if "an expert's area of expertise is adjacent . . . to the subject matter of his testimony," he may be deemed unqualified if his expertise does not actually encompass that subject matter.[47] Any testimony outside the expert's area of expertise must be stricken.[48]

Only reliable testimony may be presented to jurors.[49] The reliability requirement "applies to all aspects of an expert's testimony: the methodology, the facts underlying the expert's opinion, [and] the link between the facts and the

[45] *Voilas v. Gen. Motors Corp.*, 73 F. Supp. 2d 452 (D.N.J. 1999) (citing *United States v. Velasquez*, 64 F.3d 844, 849 (3d Cir. 1995)).

[46] *Elock v. Kmart Corp.*, 233 F.3d 734, 743 (3d Cir. 2000) (quoting *Waldorf v. Shuta*, 142 F.3d 601, 625 (3d Cir. 1998)).

[47] *D&D Assocs., Inc. v. Bd. of Educ. of N. Plainfield*, No. Civ. A. 03-1026(MLC), 2006 WL 755984, at *3 (D.N.J. Mar. 20, 2006).

[48] *Fireman's Fund Ins. Co. v. Videfreeze Corp.*, 540 F.2d 1171, 1180 (3d Cir. 1976).

[49] *Tyger v. Precision Drilling Corp.*, 832 F. App'x 108, 111–12 (3d Cir. 2020).

conclusion."[50] "An expert's opinion may be unreliable if he fails to account for contrary scientific literature and instead 'selectively chooses his support from the scientific landscape.'"[51] "Cherry-picking is a form of result-driven analysis which undermines principles of the scientific method by applying methodologies (valid or otherwise) in an unreliable fashion."[52] The reliability of an expert's opinion must therefore "be seriously questioned when it is shown that the expert formed his or her opinion prior to reviewing scientific evidence, and, thereafter, merely cherry-picked evidence favorable to that opinion."[53]

"In addition to reliability, Rule 702 requires that the expert's testimony must assist the trier of fact."[54] There must be a "connection between the scientific research or test result to be presented and a particular disputed factual issues in the case."[55] "[E]ven if an expert's proposed testimony constitutes scientific knowledge, his or

[50] *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 291 (3d Cir. 2012) (quoting *Heller v. Shaw Indus., Inc.*, 167 F.3d 146, 155 (3d Cir. 1999)).

[51] *In re Zoloft (Setraline Hydrochloride) Prod. Liab. Litig.*, 26 F. Supp. 3d 449, 459 n.30 (E.D. Pa. 2014) (quoting *In re Rezulin Prod. Liab. Litig.*, 369 F. Supp. 2d 398, 425 (S.D.N.Y. 2005)).

[52] *In re Acetaminophen – ASD-ADHD Prod. Liab. Litig.*, __ F. Supp. 3d __, 2023 WL 8711617, *17-18 (S.D.N.Y. 2023) (internal citations omitted).

[53] *In re Seroquel Prods. Liab. Litig.*, No. 06-1769, 2009 WL 3806434, *5 (M.D. Fla. June 18, 2009).

[54] *In re Paoli R.R. Yar PCB Litig.*, 35 F.3d 717, 742-43 (3d Cir. 1994).

[55] *United States v. Downing*, 753 F.2d 1224, 1241 (3d Cir. 1985).

her testimony will be excluded if it is not scientific knowledge for purposes of the case."[56] The expert's testimony must thus "fit" the case.[57]

A. Dr. Su's opinions should be excluded as his deposition testimony and post-report testing cannot cure the deficiencies in his report.

During his deposition, Dr. Su revealed that he conducted and relies on several tests that he first performed *after* he issued his expert report. That he issued his expert report without having first conducted those tests reveals that the opinions he expressed in his report were based on speculation and that lacking any data—let alone reliable data—his analysis was results-driven and not methodologically sound. The exclusion of Dr. Su's testimony is therefore necessary but not sufficient. His report should also be excluded as the positions taken by Dr. Su during his deposition contradict the opinions he expressed in his report.

Federal Rule of Civil Procedure 26(a)(2)(B) is "deceptively simple."[58] It requires the disclosure of six categories of information:

1. A complete statement of all opinions that will be expressed at trial and the reasons and basis for the opinion[s];
2. The data and information considered by the expert;
3. Any exhibits the expert will use;
4. Qualifications of the expert, including publications for the past ten years;
5. Compensation; and

[56] *Paoli*, 35 F.3d at 743.

[57] *Id.*

[58] *Reed v. Binder*, 165 F.R.D. 424, 428 (D.N.J. 1996).

6. A list of other cases in which the expert has testified during the previous four years.[59]

To understand the requirements of Rule 26(a)(2)(B), it is necessary to read it in conjunction with Rule 26(b)(4)(A), which provides that "[i]f a report from the expert is required under subdivision (a)(2)(B), the deposition shall not be conducted until after the report is provided." These Rules serve several ends. "The requirement under subdivision (a)(2)(B) of a complete and detailed report of the expected testimony of certain . . . experts may . . . eliminate the need for some such depositions or at least reduce the length of the depositions."[60] These requirements aim to eliminate "unfair surprise to the opposing party and the conservation of resources."[61] The test of a report is therefore "whether it was sufficiently complete, detailed and in compliance with the Rules so that surprise is eliminated, unnecessary depositions are avoided and costs are reduced."[62] "Rule 26(a)(2) does not allow parties to cure deficient expert reports by supplementing them with later deposition testimony."[63]

[59] *Reed*, 165 F.R.D. at 428-29 (quoting Fed. R. Civ. P. 26(a)(2)(B)).

[60] *Reed*, 165 F.R.D. at 429.

[61] *Id.* (quoting *Sylla-Sawdon v. Uniroyal Goodrich Tire Co.*, 47 F.3d 277, 284 (8th Cir. 1995)).

[62] *Id.*

[63] *Mills v. Ethicon, Inc.*, 678 F. Supp. 3d (D.N.J. 2023) (quoting *Ciomber v. Coop. Plus, Inc.*, 527 F.3d 635, 642 (7th Cir. 2008)).

To allow a party to cure the deficiencies in the report of its expert would after all "completely undermine" the requirements and goals Rule 26(a)(2).[64]

Some courts have found that the exclusion of the expert's opinion is "automatic and mandatory" under Rule 26(a)(2) unless the offending party can establish that the violation was either "justified or harmless."[65] The Third Circuit has however identified several factors that district courts should weigh in considering whether to strike an expert's disclosure: "(1) the surprise or prejudice; (2) the ability of the moving party to cure any such prejudice; (3) the extent to which allowing the testimony would disrupt the order and efficiency of trial; (4) bad faith or willfulness in failing to comply with the court's order; and (5) the importance of the testimony sought to be excluded."[66] Each of these factors is satisfied here.

In his May 21, 2024 expert report, Dr. Su described the "central stop dispersion staining technique by PLM" as a "standard operating procedure" that can "quickly and accurately measure the refractive index (RI) of asbestos minerals[.]"[67] Dr. Su ultimately concludes that Dr. Longo failed to accurately identify RI values based on his "review of the reports identified in Exhibit B[.]"[68] Not once in his report

[64] *Id.* (quoting *Ciomber*, 527 F.3d at 642).

[65] *Ciomber*, 527 F.3d at 641

[66] *Dandy v. Ethicon Women's Health and Urology*, 579 F. Supp. 3d 625, 629 (D.N.J. 2022).

[67] **Exhibit 6**, 5/21/2024 Su Report, pg. 2.

[68] *Id.*, pg. 4.

did Dr. Su suggest that the "central stop dispersion staining technique" could not accurately measure the RI values of the particles Dr. Longo tested. He rather notes that the "central stop dispersion staining technique" has been called the "Su Method" "by scientists practicing in this area and has been cited in textbooks addressing the identification of asbestos by PLM."[69]

Despite referring to the "central stop dispersion staining" technique as "accurate" in both his report and publications,[70] Dr. Su took another—and, in fact, contrary—position on the use of "central stop dispersion staining" during his deposition. During his deposition, Dr. Su for the first time stated that the "Becke line" method is a "separate method,"[71] which he also described as the "traditional" and the "foremost" method for determining the RI value of asbestos particles.[72] As he explained, if you "are in doubt which color is the right one to use, you switch that to the no stop and you close the aperture diaphragm to examine Becke line."[73] Then when asked whether one can be following the "Su Method" without cross-

[69] *Id.*, pg. 4.

[70] **Exhibits 6** and **9**.

[71] **Exhibit 8**, 7/18/2024 Su. Tr., T200:15-18.

[72] **Exhibit 7**, 7/11/ 2024 Su Tr., T100:11-14. Although Dr. Su has described the "Becke line" technique as a "traditional" method, he acknowledged that he first published the "Becke line" methodology in 2023 and also that he is not aware of any other published literature that suggests that the Becke line analysis should be used in conjunction with the dispersion staining method to determine the refractive index of a mineral. **Exhibit 8**, 7/18/2024 Su. Tr., T219:14to T220:17, T226:11-14, T306:1-6.

[73] **Exhibit 7**, 7/11/ 2024 Su Tr., T100:3-6.

referencing the central stop dispersion staining analysis with the Becke line analysis, Dr. Su responded that one should "automatically" check with another method.[74] So while Dr. Su testified that one should cross-reference the Becke line "automatically,"[75] he never described performing a Becke line analysis in his report. Nor did he mention the need for a Becke line analysis in his report. The first time Dr. Su mentioned Becke line analysis was during his deposition, during which he described performing tests after he issued his report.[76] Dr. Su however never supplemented his report.[77]

Dr. Su's discussion of the Becke line analysis was not the only instance in which he went beyond clarifying his report to supplementing it.[78] In his report, Dr. Su stated that "MAS routinely uses insufficient light intensity, as if the light intensity was suppressed, which in turn subdues the dispersion staining color, resulting in a subdued RI value and a subdued birefringence value."[79] According to Dr. Su, he first "theorized" that Dr. Longo used insufficient lighting in January 2022.[80] Explaining

[74] *Id.*, T130:18 to T131-4.

[75] *Id.*, T131:4-5.

[76] *Id.*, T101:9-11. Dr. Su has admitted that he first conducted the tests he performed in Pittsburgh with Dr. Sanchez after he witnessed Dr. Longo's testimony in state court. **Exhibit 8**, 7/18/2024 Su. Tr., T261:20 to T262:1.

[77] **Exhibit 8**, 7/18/2024 Su. Tr., T264:20-22.

[78] **Exhibit 23** Pittsburg Work Plan PPT.

[79] **Exhibit 6**, 5/21/2024 Su Report, pg. 3.

[80] **Exhibit 7**, 7/11/2024 Su Tr., T46:23 to T47:2.

the basis for that belief, Dr. Su testified that he based his conclusion that Dr. Longo used insufficient light intensity based on Dr. Su's ability to use "Photoshop" to brighten the images.[81] After he issued his report, Dr. Su traveled to the office of RJ Lee to use the same model of microscope used by Dr. Longo to test whether the light intensity of Dr. Longo's microscope had been suppressed.[82] No reason was provided for why Dr. Su could not have performed those tests before he issued his report. Just as Dr. Su first tested his light intensity theory after he issued his report, he also conducted tests of Calidria chrysotile asbestos for the first time in June 2024, following the issuance of his report.[83] Again, Dr. Su never explained why he waited to test his hypotheses.[84]

Given the many deficiencies in his report and the deliberate plan to remedy those deficiencies with "Pittsburgh Work Plan,"[85] Dr. Su's opinions should be excluded. Dr. Su not only failed to provide a "complete statement of all opinions" and the "data and information considered," but his testimony went beyond simply

[81] **Exhibit 7**, 7/11/2024 Su Tr., T133:23 to T134:6; **Exhibit 6**, 5/21/2024 Su Report, pg. 23.

[82] **Exhibit 7**, 7/11/2024 Su Tr., T41:10-19, T59:11-14 ("Q. When is the first time you used, quote, unquote, that microscope? A. That was on the 15th of last month, June 15th.").

[83] *Id.*, T71:7-14.

[84] When asked about whether he was aware that Dr. Gunter's tests of Calidria had produced central stop dispersion staining colors similar to what Dr. Longo had found, Dr. Su responded that he was aware but that he was "not interested in other people's analysis" as he was to see for himself. *Id.*, T36:14-24. One would think that wanting to see for himself, Dr. Su would have tested his hypotheses before issuing his report.

[85] **Exhibit 23** Pittsburg Work Plan PPT.

clarifying his opinions to changing them—perhaps strategically given the other depositions that were taken between the date his report was first issued and his deposition was taken. As the requirements of Rule 26(a)(2) were designed to eliminate unfair surprise, Dr. Su's entirely new opinions should be excluded. And because many of those new opinions were made necessary by Dr. Su's failure to offer anything but speculation in his report for his various conclusions, the exclusion of his report in its entirety is appropriate.

B. The methodologies employed by Dr. Su render his opinions unreliable.

1. Dr. Su's employs a subjective methodology that is not reproducible.

To be reliable, an expert's methodology must be reproducible and cannot rest on subjective belief or unsupported speculation.[86] Dr. Su's methodology fails that test. As he explains, there is a procedure that analysts can follow to measure RI values up to a point.[87] Asked whether an analysist following the Su Method could "get to a point . . . where the analyst has to make an interpretation of what they are seeing," Dr. Su said "yes."[88] When then asked whether reasonable scientists could disagree on the interpretation of the colors they are seeing, Dr. Su testified that "you

[86] *Greenwalk Caterers Inc. v. Lancaster Host, LLC*, __ F. Supp. 3d __, 2023 WL 7021239, * 7 (E.D. Pa. 2023).

[87] **Exhibit 7**, 7/11/2024 Su Tr., T128:15-21.

[88] *Id.*, T128:22 to T129:4.

have to check Becke line[s].”[89] Again, though, Dr. Su never mentioned Becke lines in his report; he clearly stated that the central stop dispersion staining technique can “accurately measure the refractive index (RI) of asbestos minerals.”[90]

2. Dr. Su’s opinions are unreliable as he cherry-picks evidence and relies on results-driven speculation and *ipse dixit*.

In his academic writing, Dr. Su stated that “there are chrysotile minerals whose RIs are significantly higher than those of the standard chrysotile from the NIST SRM 1866 set.”[91] During his deposition, he similarly acknowledged that “chrysotile is a family of minerals [that] depending on where it comes from may have a different refractive index than chrysotile from another place in the world.”[92] So as he admitted, chrysotile “taken from Canada . . . may have a different refractive index than chrysotile taken from somewhere else[.]”[93] So while recognizing that there is a “range” of RI values for Chrysotile asbestos, Dr. Su believes that what Dr. Longo identified as Chrysotile falls outside of that range.

[89] *Id.*, T129:9-21.

[90] **Exhibit 6**, 5/21/2024 Su Report, pg. 2.

[91] **Exhibit 9**, pg. 56.

[92] **Exhibit 7**, 7/11/2024 Su Tr., T69:12-16.

[93] **Exhibit 7**, 7/11/2024 Su Tr., T69:17-18.

To explain that discrepancy, Dr. Su had one "reference point": EPA600/R-93/116.[94] While Dr. Su correctly notes that EPA600/R-93/116 references the NIST SRM 1866 standard,[95] he overlooks that the NIST SRM 1866 standard acknowledges that "various conditions, such as geographic origin or acid/heat treatment of the asbestos, could cause the optical properties of the asbestos in bulk insulation samples to vary considerably from the materials comprising this SRM."[96] In failing to acknowledge that, Dr. Su glossed over the contrary scientific literature.

Dr. Su's opinion that the samples tested by Dr. Longo fall outside the accepted range for chrysotile asbestos indeed warrants questioning for several other reasons. First, Dr. Su has never analyzed the refractive index of chrysotile originating from Vermont.[97] Second, before issuing his report, he had never tested a sample of Calidria.[98] Third, Dr. Su has never measured the refractive index of "chrysotile found naturally in a cosmetic talc product," which is significant as the NIST SRM 1866

[94] *Id*., T70:1-23.

[95] **Exhibit 24** NIST SRM 1866 standard.

[96] *Id.*, pg. 1.

[97] **Exhibit 7**, 7/11/2024 Su Tr., T75:8-11.

[98] *Id.*, T71:7-14. In his October 9, 2023 Supplemental Expert Report, Dr. Longo reporting testing samples of bentonite clay that he spiked with Calidria asbestos. **Exhibit 25**, pgs. 3-4. Dr. Longo explained that the samples of the spiked bentonite clay corroborate his test results. *Id.*, pgs. 5-6. When asked about this, Dr. Su confirmed that he has not tested the samples of bentonite clay spiked with Calidria asbestos. **Exhibit 8**, 7/18/2024 Su Tr., T316:15 to T317:21. When further asked why he believes that what Dr. Longo identified in the spiked bentonite clay is not chrysotile given that the sample contains only bentonite clay and Calidria, Dr. Su could only respond that MAS is "incapable of correctly perform[ing] that procedure." *Id.*, T318:1 to T319:19. As this shows, having not tested the samples himself, Dr. Su could only speculate.

standard deals with commercial-grade asbestos materials[99] and Dr. Su has not seen any literature or reports discussing the RI values for chrysotile found naturally in cosmetic talc products.[100] In fact, Dr. Su admits that he has "no idea" what the refractive index would be for an inclusion of chrysotile in cosmetic talc.[101] That Dr. Su has "no idea" what the refractive index of an inclusion of chrysotile would be confirms that his opinion is *ipse dixit* and should be excluded.

Consider another example of Dr. Su's speculation. Citing little more than a handful of Dr. Su's test results and the weight recovery fractions Dr. Su stated that the samples are "illustrative of the high degree of variation in the sample preparation procedure as well as the inability of MAS's sample preparation procedure to effectively concentrate the 'chrysotile' that it claims to find in Johnson's Baby Powder."[102] As he explains, MAS's heavy liquid separation procedure "produced a series of extremely inconsistent light fractions ranging from 13.4% to 24.2%."[103] He then noted that the "Baby Powder samples consist[ed] of 99% talcum powder" asked, "how possible is the light fraction more than 1%?" Answering that question, he said that "[i]t is beyond comprehension that those ridiculous two-digit light

[99] **Exhibit 24**, pg. 1.

[100] **Exhibit 7**, 7/11/2024 Su Tr., T164:1-6.

[101] *Id.*, T165:7-23.

[102] **Exhibit 6**, 5/21/2024 Su Report, pg. 11.

[103] *Id.*

fractions results did not make MAS realize something was grossly wrong with each and every sample preparation procedure that it tried over the course of five years."[104]

Asked about the basis for his belief that Baby Powder was 99.9% talcum powder," Dr. Su responded that Dr. Longo's report told him.[105] Dr. Su thus testified that "because MAS didn't report the amount of nickel or carbonates or whatever else might be present," he "took that to mean that it was chrysotile and talc and nothing else."[106] He further admitted that he had seen no documents reporting how much talc was in Baby Powder. That being so, Dr. Su's opinion that MAS "was grossly wrong" was based on no more than an assumption.

C. The methodologies employed by Dr. Sanchez render his opinions unreliable.

1. Dr. Sanchez is not qualified to opine on whether "asbestiform" and "non-asbestiform" particles have different health effects.

Relying on just four epidemiological studies, Dr. Sanchez advocates for an overly restrictive definition of "asbestos" that counts many asbestiform particles as non-asbestiform. His opinion is however uninformed, unreliable, and a poor fit with this case. According to the USGS, "[a]sbestos has been defined by workers in many disciplines including those in the commercial asbestos industry and the mining

[104] *Id.*, pgs. 10-11.

[105] **Exhibit 8**, 7/18/2024 Su. Tr., T248:9 to T249:3.

[106] *Id.*, T252:6-10.

industry, the public health community, those in the regulatory community, and the mineralogical and geological sciences."[107] The definition of "asbestos" and related terminology can thus "vary depending on the source and purpose."[108] And so, a definition of "asbestos" appropriate in one setting "could be vastly different from those used in the health community."[109, 110]

To understand Dr. Sanchez's opinion, it is necessary to appreciate his limitations.[111] Dr. Sanchez is not an epidemiologist or a healthcare professional.[112] Dr. Sanchez nonetheless relies on "epidemiological studies" in his opinion,[113] even

[107] **Exhibit 26**, pg. 37.

[108] **Exhibit 26**, USGS Open File Report, pg. 37; *see also* Longo Exhibit 28, pg. 71 (Interagency Working Group on Asbestos in Consumer Products: noting that varying definitions of "asbestos" exist because of the "differences in the situations each agency regulates, differences in the sample matrices subject to testing (e.g., air, water, soil, bulk samples, building materials, or processed consumer products), varying needs for sensitivity and specificity, an evolving understanding of what information is necessary to address health concerns in various situations, and the influence of non-government stakeholders.").

[109] **Exhibit 26**, pg. 37.

[110] In its 2021 White Paper, "IWGACP Scientific Opinions on Testing Methods for Asbestos in Cosmetic Products Containing Talc," the IWGACP noted that it "is still debatable" whether "there are differences in potency between asbestiform and non-asbestiform particles". **Exhibit 27** (Longo Exhibit 28), pg. 71

[111] **Exhibit 27**, pg. 42 ("it seems appropriate in light of the issues addressed in this report, to stress that it is absolutely not the role of the analytical or mineralogical communities to make health-based decisions or to make independent analytical assessments").

[112] **Exhibit 10**, pg. 5 ("I am not a professional epidemiologist[.]"); **Exhibit 12**, 6/25/2024 Sanchez Tr., 53:19-20 ("I'm not a medical doctor").

[113] **Exhibit 10**, pg. 5; *see also* **Exhibit 12**, 6/25/2024 Sanchez Tr., T204:7-17 ("You asked me a question regarding a statement that I know to be inaccurate based upon other testing that is out there in the medical field[.]").

though, by his own admission, that is outside his area of expertise.[114] His lack of training and experience in epidemiology is, as a consequence, readily apparent from the fact that he considered only four studies and failed to consider any of the Bradford Hill factors in his analysis.[115] Moreover, by trying to align a mineralogic definition of "asbestos" with the health effects of asbestos, such that no health effects could result if the requirements of his definition of "asbestos" are not satisfied, Dr. Sanchez's opinion require an inferential leap. As he cannot bridge that "analytical gap," his opinion risks misleading the jury and does not fit this case.[116] Dr. Sanchez's opinion on whether "asbestiform" and "non-asbestiform" particles have different health effects should therefore be excluded.[117]

2. Dr. Sanchez's methodology for identifying asbestos is subjective, unreliable and not accepted in the scientific community.

While Dr. Sanchez cites several standards, including OSHA ID 191,[118] EPA600/R-93/116,[119] and ISO 22262-1,[120] in defining "asbestos," he fails to note

[114] **Exhibit 12**, 6/25/2024 Sanchez Tr., 251:7-10.

[115] **Exhibit 10**, pg. 5.

[116] *See General Elec. Co. v. Joiner*, 522 U.S. 136, 147 (1997).

[117] **Exhibit 26**, pg. 42 ("it seems appropriate in light of the issues addressed in this report, to stress that it is absolutely not the role of the analytical or mineralogical communities to make health-based decisions or to make independent analytical assessments").

[118] **Exhibit 14**.

[119] **Exhibit 15**.

[120] **Exhibit 16**.

the limitations of those standards and ultimately deviates from those standards and the literature by defining "asbestos" in the most restrictive manner possible. Dr. Sanchez's reliance on three standards with varying requirements moreover confirms that his methodology is subjective and non-reproduceable.[121]

For instance, Dr. Sanchez fails to note that OSHA ID 191 "was specifically designed to identify commercial-grade asbestos found in the workplace and in commercial products."[122] Nor does Dr. Sanchez reckon with the fact that OSHA has cautioned that "when the analyst is in doubt the particle should be counted."[123]

Dr. Sanchez similarly fails to address how EPA 600/R-93/116 was "designed to detect commercially processed asbestos in items like floor tiles, roofing felts, paper insulation, paints, and mastics, not naturally occurring asbestos on air filters or in soil samples."[124] The EPA has indeed rejected Dr. Sanchez's position here that a 3:1 aspect ratio cannot be used to differentiate between asbestos and non-asbestiform minerals, which he bases on ISO 10312.[125] According to the EPA in a response to a report prepared by Dr. Sanchez's employer, RJ Lee, ISO 10312

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[121] *See Whyte v. Stanley Black & Decker, Inc.*, 514 F. Supp. 3d 684, 696 (W.D. Pa. 2021) (expert's reliance on an industry standard in giving his opinion without explanation of how the expert implemented the standard renders the opinion unreliable).

[122] **Exhibit 26**, pg. 40.

[123] **Exhibit 26**, pg. 37.

[124] **Exhibit 28**, pg. 7.

[125] **Exhibit 10**, pg. 22.

"clearly authorize[s] the counting of PCME structures with a 3:1 aspect ratio if the data are to be used for exposure or risk assessment purposes[.]"[126] In that report, the EPA added that Dr. Sanchez's employer, RJ Lee, also "manipulate[d] its statistical analysis of the El Dorado Hills air data by ignoring counts of asbestos fiber bundles in its evaluations."[127] To that end, the EPA noted that "[b]undles are two or more attached parallel asbestos fibers which can have a significant health impact when they are inhaled and separated into individual fibers."[128] Just as history tends to repeat itself, Dr. Sanchez claims that "Dr. Longo's report also fails to identify how he identified the particular structures as bundles[.]"[129] Other than noting what the definition of a bundle is, Dr. Sanchez fails to substantiate in any way his insinuation that Dr. Longo incorrectly identified bundles.

While Dr. Sanchez quotes ISO 22262-1's section on "Morphology," Dr. Sanchez overlooks that the morphology of asbestos as described is "characteristic of the larger fibers seen."[130] He similarly neglects that ISO 22262-1's "Morphology" section "is intended as guidance for analysists to discriminate between non-asbestiform and asbestiform amphibole populations" and is "not intended to override

[126] **Exhibit 28**, pg. 6.

[127] *Id.*, pg. 7.

[128] *Id.*, pg. 7.

[129] **Exhibit 10**, pg. 22.

[130] **Exhibit 16**, pg. 22.

the definition of asbestos as presented in 2.9 nor to override any national regulation."[131] Dr. Sanchez also misquotes ISO 22262-1 when he states: "no assumptions can be made as to whether observed anthophyllite, tremolite, and actinolite are asbestiform." [132] ISO 22262-1 rather states that "no assumption can be made as to whether the amphibole is asbestiform or non-asbestiform."[133] While his paraphrasing of ISO 22262-1 may seem minor, it reflects a consistent and comprehensive approach to the identification of "asbestos" that is overly restrictive and thus outside accepted scientific standards and norms as it skews his analysis.

Dr. Sanchez moreover employs an ever-shifting definition of what constitutes a "population." Dr. Sanchez testified his methodology requires him to "look at as many particles you can find" to examine whether the morphological features associated with asbestos are present.[134] He also explained that if he does not "have enough data at the end of the analysis" such that he "wasn't confident whether or not it was asbestos or whether it was a non-asbestos amphibole," he "would look at the sample more."[135] For Dr. Sanchez, a "population" is thus subjective as "no single particle will exhibit all attributes of a population."[136] It can be as small or large as he

[131] *Id.*, pg. 22.

[132] **Exhibit 10**, pg. 22.

[133] **Exhibit 16**, ISO 22262-1, pg. 23.

[134] **Exhibit 12**, 6/25/2024 Sanchez Tr., T349:18 to T350-5.

[135] *Id.*, T352:4-23.

[136] *Id.*, 340:7-16.

feels necessary. And without any standards for what constitutes a population, Dr. Sanchez can avoid "the one fiber problem,"[137] which allows him to describe an individual particle as not being asbestos even though it may have nearly all the morphological characteristics of asbestos, which he has acknowledged becomes more likely as the size of a particle decreases.[138] Yet when it would produce a negative finding of asbestos, Dr. Sanchez has deviated from this population-oriented approach and conducted a "one-to-one" examination.[139] His results-driven methodology is therefore subjective, not reproducible, and unreliable.

3. Dr. Sanchez's cherry-picking of test results renders his opinions unreliable.

Dr. Sanchez reached his conclusions using flawed methods, including the "cherry-picking" of test results to support Defendants' position. Dr. Sanchez also states that he reviewed "numerous independent testing results by McCrone Laboratories, RJ Lee Group, and other third-party testers" and that "[t]hese results show that these experts have consistently determined that Johnson & Johnson's talcum powder was not contaminated with asbestos."[140] He however ignores many

[137] *Id.*, T352:19-23.

[138] **Exhibit 12**, 6/25/2024 Sanchez Tr., T356:17-21. According to the Working Group on Asbestos in Consumer Products, many particles of interest may be excluded from analysis thus leading to underreporting and false negatives, particularly "when testing a talc-containing cosmetic product that has been milled and processed." **Exhibit 27**, pg. 76.

[139] **Exhibit 10**, pg. 22.

[140] **Exhibit 10**, pg. 11.

contrary test results, including ones reporting the presence of chrysotile asbestos.[141] Dr. Sanchez's selective disregard or ignorance of these test results undermines the reliability of his analysis thereby rendering his opinion unreliable. Indeed, Dr. Sanchez states that while there have been "occasional report[s] of non-asbestiform tremolite/actinolite," there have "never [been] any reports of anthophyllite."[142] That is not however correct.[143]

When Dr. Sanchez cannot ignore test results, such as the EPA's 2019 finding of chrysotile in Baby Powder, Dr. Sanchez speculates that the positive results were caused by contamination.[144] He also claims that his employer, RJ Lee, could not "duplicate the findings of chrysotile[.]" In doing so, he overlooks the "[f]or cosmetics, it appears that any given type of mineral particle in the same at a relatively low level will not necessarily be homogeneously distributed and that the number of visualized particles will tend to be small."[145] And so, because TEM "[m]ay not see fibers at low concentrations" and PLM may underreport smaller particles,[146] Dr.

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[141] *See* **Exhibit 13** (identifying test results of chrysotile asbestos: 3/9/1971 McCrone ;10/12/1971 McCrone; 1972 University of Minnesota; 8/24/1972 Sperry Rand (hired by the FDA); 8/3/1972 Dr. Weissler (hired by the FDA); 1/29/1974 McCrone; 3/11/1974 McCrone; 4/10/1974 McCrone; 4/24/1974 McCrone; 5/8/1974 McCrone; 7/1/1975 McCrone; 10/6/1978 McCrone; 8/22/1985 McCrone; 4/29/1986 McCrone; 3/14/1988 RJ Lee; 11/26/1990 McCrone).

[142] **Exhibit 10**, pg. 7.

[143] *See* **Exhibit 13**.

[144] **Exhibit 10**, pgs. 13-14.

[145] **Exhibit 27**, pg. 77.

[146] *Id.*, pgs. 70, 76.

Sanchez's criticisms of the 2019 EPA findings lack measurable confidence limits and fail to consider the uncertainties in sampling and measurement of asbestos.

4. Dr. Sanchez's opinion that "contamination would be a sporadic event" is based on speculation, not empirical data.

Dr. Sanchez's opinion that "contamination would be a sporadic event" is not constructed on empirical or historical data but speculation.[147] According to Dr. Sanchez, "[s]everal things must happen for asbestos contamination to occur in a finished talc-containing product[,]" with the first step being that there must be asbestos "in the area being mined."[148] Speaking to this, Dr. Sanchez conceded in his deposition that "as you look up and down the whole Appalachian chain of mountains, especially in Vermont, yes, there are plenty of occurrences of . . . asbestos in those areas[.]"[149] Dr. Sanchez however explained that "when you actually look at the literature involving the Hammondville mine operated by Johnson & Johnson, the earlier dates of that mine as reported by Chidester was an open mine, [had] very poor quality talc" and that it "wasn't until they got deeper in into the core and into new areas that they found the higher purity talc ores that they converted to going underground and producing potential cosmetic grade talcs from."[150] Dr.

[147] **Exhibit 10**, pgs. 3-4.

[148] *Id.*, pg. 3.

[149] **Exhibit 12**, 6/25/2024 Sanchez Tr., T267:16 to T268:6.

[150] *Id.*, T269:10-21.

Sanchez thus reasoned "that the quality of the talc, the nature of the talc deposit varied between earlier uses of the quarry and the later uses."[151]

Casting doubt on his opinion here even further, Dr. Sanchez admitted that he had not previously seen a memorandum dated October 27, 1992 from Luzenac.[152] In that memorandum, JP Grange stated:

> The mining method is the major problem in Vermont. The orebodies contain a variety of ores with very different qualities. The ore changes completely on very short distances. A highly selective mining method must be enforced in order to supply the right ore grade to each end product.[153]

When asked whether he could contradict what was said in his memorandum, Dr. Sanchez testified that he had "no knowledge of J&J business practices, internal corporate decision-making of any nature."[154]

Dr. Sanchez also reasoned that for asbestos to reach the finished end-product, "non-talc rock, which contains asbestos must survive the milling [or beneficiation] processes that are designed to remove impurities from the talc."[155] In response to questioning about Johnson & Johnson's beneficiation process, Dr. Sanchez testified

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[151] *Id.*, T269:23 to T270-7.

[152] **Exhibit 29**; **Exhibit 12**, 6/25/2024 Sanchez Tr., T316:1 to T323:10.

[153] **Exhibit 29**, pg. 1.

[154] **Exhibit 12**, 6/25/2024 Sanchez Tr., T323:8-10.

[155] **Exhibit 10**, pgs. 3-4.

that he relied on Johnson & Johnson's historical records, which were provided to him.[156] But he also acknowledged that he spoke to no one at Johnson & Johnson about the beneficiation processes that were used.[157] And crucially, Dr. Sanchez admitted that he has seen no data on the failure rate of the beneficiation process for removing accessory minerals from the talc.[158] Lacking such data, Dr. Sanchez can only speculate about the effectiveness of the beneficiation process and the likelihood that the end-product would be contaminated.

5. Dr. Sanchez's criticisms of Drs. Kessler and Sage's regulatory opinions are neither sound nor relevant.

Tasked with reviewing select paragraphs of Dr. Kessler's report,[159] Dr. Sanchez reveals again the limits of his expertise and his cherry-picking of test results. Those deficiencies not only render his opinion unreliable but also ensure that his critique of Dr. Kessler's report will do more to mislead jurors than assist them. According to Dr. Sanchez, "Dr. Kessler's opinions on geology and testing are without a sound basis" as he has "specifically addressed what is and is not asbestos as established in both the scientific and regulatory literature in my expert reports on behalf of Johnson & Johnson."[160] But as Dr. Kessler explains, a "determination by a

[156] **Exhibit 12**, 6/25/2024 Sanchez Tr., T173:8-23.

[157] *Id.*, T166:18 to T167:3.

[158] *Id.*, T178:7-12.

[159] **Exhibit 17**, Sanchez 4/1/2024 Report, pg. 1.

[160] *Id.*

laboratory that certain amphibole particles were non-asbestiform in nature does not mean the safety of those non-asbestiform amphiboles was substantiated."[161] Moreover, unlike Dr. Kessler, Dr. Sanchez is not a medical doctor and has not conducted a comprehensive epidemiological review of asbestos. Dr. Sanchez is thus not qualified to rebut Dr. Kessler's opinion.

Dr. Sanchez's opinion is also a poor fit. In his report, Dr. Kessler cites 21 CFR § 740.10 to explain that since March 3, 1975, the FDA's regulations require that "[e]ach ingredient used in a cosmetic product and each finished cosmetic product shall be adequately substantiated for safety prior to marketing."[162] The regulations further state that "[a]ny such ingredient or product whose safety is not adequately substantiated prior to marketing is misbranded unless it contains the following conspicuous, statement on the principal display panel: Warning-The safety of this product has not been determined."[163] Therefore, according to Dr. Kessler, "a cosmetic manufacturer has a responsibility to substantiate the safety of their product or must warn consumers that the safety of their product has not been determined or not sell the product.[164] As he further explains, "if a health hazard may be associated with the product, a cosmetic manufacturer must include a warning on their

[161] **Exhibit 4**, Kessler 11/15/2023 Kessler Report, ¶ 103.

[162] *Id.*, ¶ 27 (citing 21 CFR § 740.10).

[163] *Id.*, ¶ 27 (citing 21 CFR § 740.10).

[164] *Id.*, ¶ 46.

product."[165] Dr. Sanchez does not address this aspect of Dr. Kessler's opinion. He rather disputes whether asbestos has been found in absolute terms but that does not disprove Dr. Kessler's opinion. That, however, misses Dr. Kessler's point.

Dr. Kessler, to be sure, acknowledges that "all laboratory tests have some limitations and can be 'explained away."[166] Recognizing that, Dr. Kessler states that his opinions "are based on the totality of evidence JNJ and its affiliates accumulated over 50 years, not on any one laboratory test or set of tests."[167] Dr. Kessler then recounts decades of Johnson & Johnson's historical testing, including its test results that were positive for asbestos, which were confirmed by Johnson & Johnson's 30(b)(6) corporate representative, Dr. John Hopkins.[168] So, according to Dr. Kessler, "once JNJ had evidence of a) the presence of asbestos because of its known carcinogenicity and absence of a threshold dose; or b) the presence of non-asbestiform amphiboles or fibrous talc, the safety of their product was not established."[169] And with Johnson & Johnson aware of test results since the 1970s of asbestos in its talc, the safety of its products has "not been substantiated."[170]

[165] *Id.*, ¶ 47.

[166] *Id.*, ¶ 138.

[167] *Id.*, ¶ 138.

[168] *Id.*, ¶¶ 168-168.11.

[169] *Id.*, pg. 117 ¶ 8.

[170] *Id.*, pg. 117 ¶ 10.

Because Dr. Sanchez misunderstands Dr. Kessler's opinions, his opinions are not methodologically sound and poorly fit the needs of this case.

The same is true of Dr. Sanchez's rebuttal of Dr. Sage's opinion. Dr. Sanchez is not qualified to dispute Dr. Sage's opinions as they pertain to regulatory compliance or medicine. As with his rebuttal of Dr. Kessler's opinion, Dr. Sanchez claims that Dr. Sage's "opinions on geology, mineralogy, and analytical testing are without a sound basis."[171] And again, Dr. Sanchez's opinion is wide of mark as Dr. Sage's findings do not depend on there being studies definitively proving that Baby Powder is dangerous to human health because it contains asbestos. Instead, citing federal regulations, Dr. Sage explained that there is "a low threshold for disclosure of risk and uncertainty because cosmetics have no offsetting health benefits and because studies are infrequent and poorly funded compared to drugs."[172] Dr. Sanchez's opinions thus poorly fit the needs of this case and are not methodologically sound.

D. The methodologies employed by Dr. Wylie render her opinions unreliable.

1. Dr. Wylie failed to follow her own methodology in testing two samples of Johnson's Baby Powder.

Dr. Wylie criticizes Dr. Longo and his team for failing to consider eleven properties that she claims to use in her "practice" to identify minerals by polarized

[171] **Exhibit 18**, Sanchez 4/1/2024 Report, pg. 1.

[172] **Exhibit 5**, 11/15/2023 Sage Report, ¶ 74 (citing 21 C.F.R. §§ 740.1, *et seq.*).

light microscopy.[173] Dr. Wylie is however not an "analyst."[174] She does not do "routine analysis of cosmetic talc."[175] In fact, over her career, Dr. Wylie has only tested two samples of Johnson's Baby Powder.[176] And while Dr. Wylie has stated that those results were negative for asbestos,[177] she did not "record the results[.]"[178] Nor did she follow the methodology she outlines in her report for identifying minerals by PLM. That is enough to require her exclusion.

Despite opining in her report that one should use TEM alongside PLM, Dr. Wylie only used PLM in testing Baby Powder.[179] And when asked about why she did not use TEM, Dr. Wylie testified that she "wasn't really testing it."[180] Her stated "goal" was rather to "to make sure that I didn't see a lot of serpentine in there." [181,]

[173] **Exhibit 19**, Wylie 5/3/2024 Report, pg. 4. Notably, in her 2019 report, Dr. Wylie says nothing about there being eleven morphological properties that must be considered, **Exhibit 20,** Wylie 2/25/19 Report.

[174] **Exhibit 21**, 6/24/2024 Wylie Tr., T32:20.

[175] *Id.*, T32:19-15.

[176] *Id.*, T10:8 to T11:7. Dr. Wylie has testified that other than these two samples, she has not tested any other cosmetic talc products for asbestos. *Id.*, T19:10-24.

[177] *Id.*., T14:7-11.

[178] *Id.*, T12:6-7.

[179] *Id.*, T14:3-14.

[180] *Id.*, T14:12-24.

[181] **Exhibit 21**, 6/24/2024 Wylie Tr., T15:7-11.

[182] She, as a result, only "made several mounts" of the sample to test.[183] And even though she was already serving as an expert for Johnson & Johnson and thought it pertinent to test a sample of Baby Powder using PLM, her failure to preserve those results denied others from testing her sample and verifying her results.

With Dr. Wylie's failure to keep and secure data from her tests of Baby Powder, it indeed cannot be known what standards she used in conducting her tests such as whether she ruled out particles from consideration due to their aspect ratio. This is a significant deviation from accepted scientific protocols. After all, Dr. Wylie has maintained that asbestos must have a 20:1 aspect ratio even though she could not identify any support for that standard.[184] She has also testified that there needs to be an "abundance of high aspect ratio particles."[185] But other than saying that an "abundance" requires that there be "many more than one," Dr. Wylie has been unable to define what is required for there to be an "abundance"; she could only explain that it "depends."[186] And lacking such clarity, it cannot be known whether Dr. Wylie's results were negative because she did not find an "abundance" of

[182] *Cf. Soldo v. Sandoz Pharm. Corp.*, 244 F. Supp. 2d 434, 528 (W.D. Pa. 2003) (quoting *Nat'l Bank of Commerce v. Dow Chem. Co.*, 965 F. Supp. 1490, 1516 (E.D. Ark. 1996) ("[t]he expert's motivation for his/her study and research is important").

[183] **Exhibit 21**, 6/24/2024 Wylie Tr., T14:1-2.

[184] **Exhibit 22**, 3/13/2019 Wylie Tr., T161:6-14.

[185] *Id.*, T238:23 to T239:4.

[186] *Id.,* T247:7-21, T248:10-11("Q Okay. But we can't say how many? A No.").

asbestos—whatever that may be—using her arbitrary and subjective definition of that term or because there were no such particles in the two samples she tested.

Dr. Wylie's failure to preserve the records of her tests of Baby Powder it also makes it impossible to determine whether she considered each of the eleven properties she claims to use in identifying minerals by PLM. While Dr. Wylie testified that she followed her methodology in testing the two samples of Baby Powder, she did so with the caveat that had she "found any serpentine," she "would have definitely used all of the methods[.]"[187] She then however acknowledged that you cannot "always" consider each of the properties.[188] And with Dr. Wylie admitting that she is unaware of any standards requiring consideration of each of the eleven properties specific to cosmetic talc and asbestos,[189] her opinion is not the product of reliable principles and methods.

2. Dr. Wylie's critique of Dr. Longo opinions based solely on the review of Dr. Longo's "raw data" rests on unsupported speculation and *ipse dixit*.

Never before in her career has Dr. Wylie critiqued the PLM results of another expert based solely on her review of the "raw data."[190] The entirety of her opinions and testimony was based on her observations of the "raw data" generated by Dr.

[187] **Exhibit 21**, 6/24/2024 Wylie Tr., T14:7-11.

[188] *Id.*, T14:11.

[189] *Id.*, T36:6-11, T28:18 to T29:1 (stating she has "no idea" whether all qualified experts use all eleven properties every time they examine a sample of cosmetic talc).

[190] *Id.*, T98:17-24.

Longo in his PLM analysis.[191] Other than the two samples that Dr. Wylie tested, which she kept no record of, Dr. Wylie conducted no tests of her own to determine whether asbestos could be found in Baby Powder. And while Dr. Wylie suggests that she had enough "raw data" from Dr. Longo for her to reach her conclusions, she did not consider each of the eleven properties she considers necessary to identify minerals by PLM, contrary to her own stated methodology.

Take for example Dr. Wylie's statement in her report that "[a]lthough not depicted in Figure 1, if a tungsten light source is utilized, a blue filter should be added above it."[192] When asked about this, Dr. Wylie responded that she has "no proof" that Dr. Longo did not use a blue filter.[193] Dr. Wylie also criticized Dr. Longo for not heating the sample to 480° to remove organic compounds.[194] Yet she cited no data showing that Dr. Longo's samples were contaminated with organic compounds. To the contrary, Dr. Wylie testified that she "saw nothing in the reports about sample preparation with which [she] found a problem."[195]

Dr. Wylie also questions Dr. Longo's analysis of Calidria chrysotile.[196] As she explains, the "optical data MAS has presented for the Coalinga chrysotile is not for

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[191] *Id.*

[192] **Exhibit 19**, Wylie 5/3/2024 Report, pg. 2.

[193] **Exhibit 21**, 6/24/2024 Wylie Tr., T27:11.

[194] **Exhibit 19**, Wylie 5/3/2024 Report, pg. 37.

[195] **Exhibit 21**, 6/24/2024 Wylie Tr., T107:15-18.

[196] **Exhibit 19**, Wylie 5/3/2024 Report, pg. 32.

chrysotile at all, but rather one of the other minerals present, such as pyroaurite and/or brucite."[197] Again, though, Dr. Wylie offers only *ipse dixit* in support of her position, Dr. Wylie relies on a sample of Coalinga chrysotile from 1978 in the University of Maryland's collection, which she tested.[198] When asked about how she knows the 1978 sample resembles the one tested by Dr. Longo from 1995, Dr. Wylie admitted that "of course" she does not know as "the deposit could vary to some extent depending upon where they were mining it."[199] Nor could she explain whether the properties of that mine might change based on the depth the sample was taken from.[200] Dr. Wylie rather testified that she knows "nothing about the mine[.]"[201]

Dr. Wylie also relied on the testing by McCrone Laboratories.[202] Yet despite remembering that McCrone had repeatedly identified asbestos in Johnson & Johnson talc samples, Dr. Wylie reviewed none of those results, describing them as "irrelevant."[203] So when the results support her client's position, she relies on them. But when they do not, they are "irrelevant." Such a results-driven analysis

[197] *Id.*, pg. 32.

[198] *Id.*, T110:8-11.

[199] *Id.*, T64:18-23.

[200] **Exhibit 21**, 6/24/2024 Wylie Tr., T64:24 to T65:3.

[201] *Id.*, T65:10-11.

[202] *Id.*, T63:12-15.

[203] *Id.*, T76:17-18.

"undermines the principles of the scientific method and is a quintessential example of applying methodologies (valid or otherwise) in an unreliable fashion."[204]

Another example of Dr. Wylie's *ipse dixit* is her opinion that the milling or other processing of cosmetic talc has no effect on the ability to identify chrysotile.[205] She did not "know the answer" to whether "the ball milling process [has] the capacity to change the ability to detect chrysotile asbestos in the final product by PLM."[206] While she does not "think" that the ball milling process could grind fibers down to a size that PLM would not pick it up, her only basis for that belief is that "mineral products that come out of mines are almost always ground by one milling process or the other[.]"[207] Dr. Wylie was however not familiar with Johnson & Johnson's ball milling process.[208] She indeed admits that she bases her opinion that ball milling will not "affect the ability to see the product in bundle[s] versus individual fibrils" on her "instincts."[209] Dr. Wylie has also admitted that she has not "looked at any studies" on the issue and that she cannot "testify within a reasonable

[204] *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Pracs. and Prods. Liab. Litig.*, 892 F.3d 624, 634 (4th Cir. 2018).

[205] **Exhibit 19**, Wylie 5/3/2024 Report, pg 32.

[206] **Exhibit 21**, 6/24/2024 Wylie Tr., T71:20 to T72:12.

[207] *Id.*, T72:15-20.

[208] *Id.*, T71:20-23._.

[209] **Exhibit 21**, 6/24/2024 Wylie Tr., T93:9-17.

degree of scientific certainty one way or the other."[210] Because she cannot do that, her opinion must be excluded.

V. CONCLUSION

For this and the other foregoing reasons, the Court should grant the PSC's motion to exclude the opinions of Drs. Su, Sanchez, and Wylie.

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[210] Exhibit __, 6/24/2024 Wylie Tr., T93:20-24.

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